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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

6751 Steger Drive
Cincinnati, OH 45237-3097

WARNING LETTER

December 9, 1999

Cin-WL-926-0

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Cliff Lehman
President & CEO
Blanchard Valley Regional Health Center
145 West Wallace St.
Findlay, OH 45840

Facility: Blanchard Valley Regional Health Center
(BVRHC)-Findlay Campus
MQSA ID#: 147280

Dear Mr. Lehman:

A representative from the State of Ohio radiation control program under contract to the Food and Drug Administration inspected your facility on November 4, 1999. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Personnel Requirements – Medical Physicist (21 CFR 900.12(a)(3))

[redacted], a medical physicist who performed mammography survey at your facility, did not meet the requirement of having a Masters degree or higher in a physical science, with 20 semester hours in physics or having a bachelor's degree or higher in physical science with no less 10 semester hours of physics, if [redacted] was qualified as a medical physicist under the FDA/MQSA interim regulations prior to April 28, 1999. This is required as indicated in 21 CFR 900.12(a)(3)(i) & (ii).

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

The other items listed in your November 4, 1999 inspection report identified, as Level 3 should also be corrected. We will verify correction of these items during our next inspection. You are not required to address the Level 3 item in your written response.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violation noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violation;
- Sample records that demonstrate proper record keeping procedures related to quality control.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Ms. Cindy Grant
Ohio Department of Health
Radiologic Technology Section
One Government Center
Suite 1320
Toledo, OH 43604

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/CGrant